K012006

JUL 1 3 2001

510(K) SUMMARY
(as required by 807.92(c))

Submitter of 510(k): **Medical Depot, Inc.**
55 Sea Lane
Farmingdale, NY 11735

Phone: **631-420-4134**
Fax: **631-420-4168**

Contact Person: **Harvey Diamond**

Date of Summary: May 1, 2001

Trade Name: Medical Depot Power Neb I

Classification Name: Nebulizer

Predicate Device:	Medical Depot Power Neb II	K003344
	John Bunn Model 510 Medication Compressor	K862628

Device Comparison/Description:

The Medical Depot Nebulizer Device is the same as our Power Neb II except with a membrane rather than a piston compressor. It is also the same as the Graham – Field Mini-Mist II which was originally cleared by John Bunn Company and has the same compressor as this device.

Intended Use:

The Medical Depot is intended to provide a source of compressed air for medical purposes for use in home health care. This device is used in conjunction with a pneumatic nebulizer to produce a fine aerosol mist of medication for respiratory therapy, for both children and adults suffering from respiratory disorders.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 3 2001

Medical Depot, Inc.
c/o Art Ward
Regulatory and Marketing Services, Inc.
962 Allegro Lane
Apollo Beach, FL 33572

Re: K012006
Medical Depot Power Neb I
Regulation Number: 868.5630
Regulatory Class: II (two)
Product Code: 73 CAF
Dated: May 1, 2001
Received: June 27, 2001

Dear Mr. Ward:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this

response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K012006

Device Name: Medical Depot Power Neb I

Indications For Use:

The Medical Depot is intended to provide a source of compressed air for medical purposes for use in home health care. This device is used in conjunction with a pneumatic nebulizer to produce a fine aerosol mist of medication for respiratory therapy, for both children and adults suffering from respiratory disorders.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K012006

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use_____

(Optional Format 1-2-96)